US010905853B2

(12) United States Patent
Lorenzo et al.

(10) Patent No.: US 10,905,853 B2
(45) Date of Patent: Feb. 2, 2021

(54) **SYSTEM AND METHOD FOR DELIVERING A CATHETER**

(71) Applicant: **DePuy Synthes Products, Inc.**, Raynham, MA (US)

(72) Inventors: **Juan Lorenzo**, Raynham, MA (US); **Kirk Johnson**, Raynham, MA (US); **Dillon Karg**, Raynham, MA (US)

(73) Assignee: **DePuy Synthes Products, Inc.**, Raynham, MA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **15/407,728**

(22) Filed: **Jan. 17, 2017**

(65) **Prior Publication Data**

US 2018/0200478 A1 Jul. 19, 2018

(51) **Int. Cl.**

A61M 25/01	(2006.01)
A61M 25/09	(2006.01)
A61M 25/00	(2006.01)
A61M 25/06	(2006.01)
A61M 25/04	(2006.01)
A61M 29/00	(2006.01)

(52) **U.S. Cl.**

CPC ***A61M 25/01*** (2013.01); ***A61M 25/0023*** (2013.01); ***A61M 25/0054*** (2013.01); ***A61M 25/04*** (2013.01); ***A61M 25/0662*** (2013.01); ***A61M 25/09*** (2013.01); *A61M 29/00* (2013.01); *A61M 2025/0024* (2013.01); *A61M 2025/0175* (2013.01); *A61M 2025/0681* (2013.01); *A61M 2025/09166* (2013.01); *A61M 2205/32* (2013.01)

(58) **Field of Classification Search**

CPC A61M 2025/0175; A61M 29/00; A61M 2029/025; A61M 25/0662; A61M 2025/0681; A61M 2025/0687; A61M 25/01; A61M 25/04; A61M 25/0023; A61M 25/0024; A61M 25/0054; A61M 25/09; A61M 2025/09166; A61M 2205/32; A61B 17/221; A61B 17/32; A61B 17/22031

See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

5,320,602	A	6/1994	Karpiel
5,389,087	A	2/1995	Miraki et al.

(Continued)

FOREIGN PATENT DOCUMENTS

WO	2011089014	A1	7/2011

OTHER PUBLICATIONS

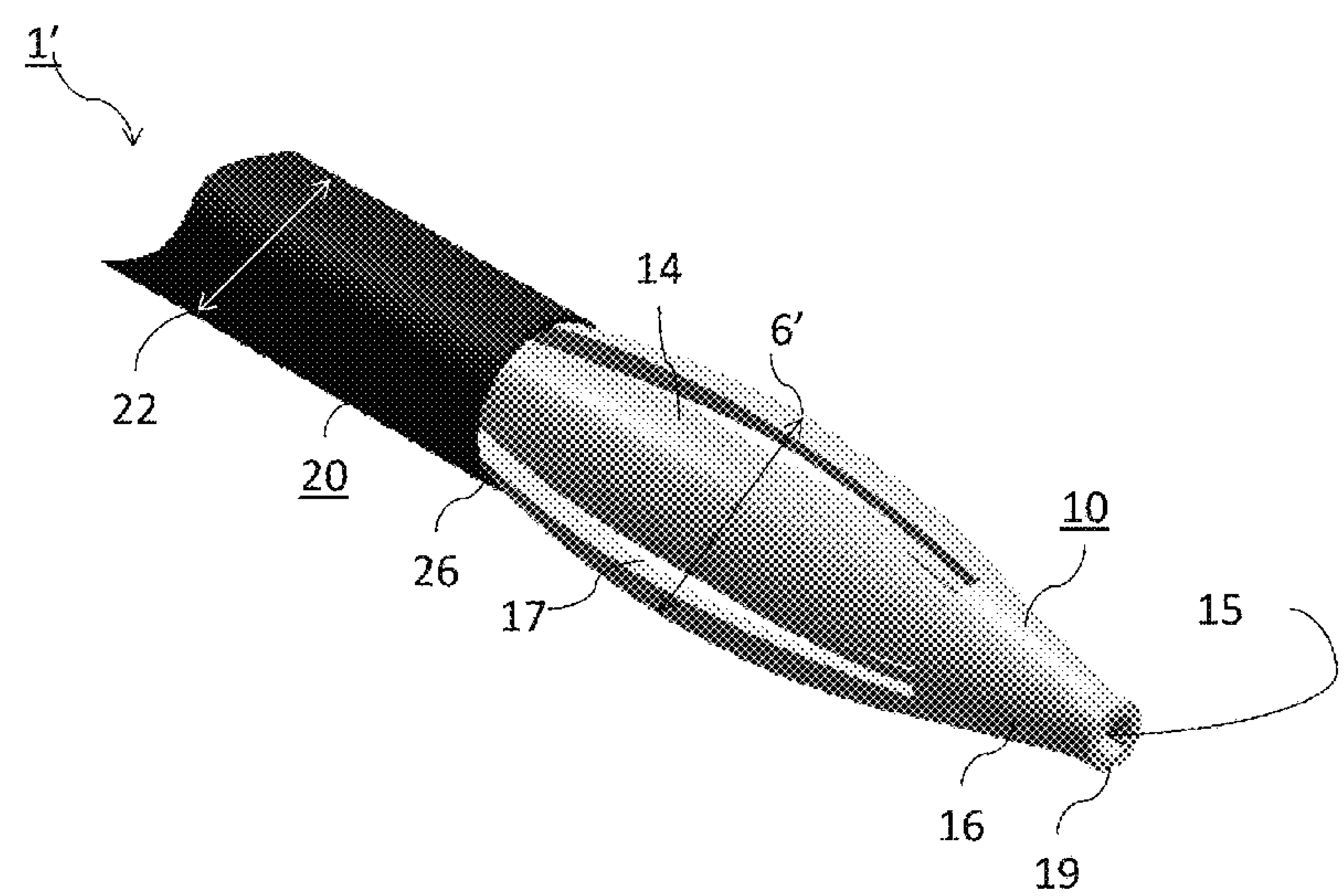
International Search Report dated Mar. 29, 2018 during the prosecution of International Application No. PCT/IB2018/050291.

Primary Examiner — Jason E Flick
Assistant Examiner — Tasnim Mehjabin Ahmed
(74) *Attorney, Agent, or Firm* — Troutman Pepper Hamilton Sanders LLP

(57) **ABSTRACT**

Systems and methods for delivering a catheter to a location of interest in the vasculature, the method including selectively positioning a guidewire at the location, positioning a self-expanding sheath within a lumen of the catheter, advancing the catheter and the self-expanding sheath in tandem over the guidewire, and distally moving a distal end of the self-expanding sheath out from an inner lumen of the catheter thereby causing the self-expanding sheath to move from a collapsed state within the catheter to an expanded state outside the catheter.

12 Claims, 9 Drawing Sheets



(56) **References Cited**

U.S. PATENT DOCUMENTS

5,447,503	A	9/1995	Miller
5,569,296	A	10/1996	Marin et al.
5,697,948	A	12/1997	Marin et al.
5,709,658	A	1/1998	Sirhan et al.
5,857,464	A	1/1999	Desai
5,902,333	A	5/1999	Roberts et al.
5,947,925	A	9/1999	Ashiya et al.
6,059,748	A	5/2000	Teirstein et al.
6,120,480	A	9/2000	Zhang et al.
6,391,037	B1	5/2002	Greenhalgh
6,527,789	B1	3/2003	Lau et al.
6,692,482	B2 *	2/2004	Heller A61M 25/00 604/103.04
7,144,386	B2	12/2006	Korkor et al.
7,731,707	B2	6/2010	Heller et al.
8,597,454	B2	12/2013	Parker et al.
9,232,992	B2	1/2016	Heidner
9,532,792	B2	1/2017	Galdonik et al.
9,532,873	B2	1/2017	Kelley
9,533,344	B2	1/2017	Monetti et al.
9,539,011	B2	1/2017	Chen et al.
9,539,022	B2	1/2017	Bowman
9,539,122	B2	1/2017	Burke et al.
9,539,382	B2	1/2017	Nelson
9,549,830	B2	1/2017	Bruszewski et al.
9,554,805	B2	1/2017	Tompkins et al.
9,561,125	B2	2/2017	Bowman et al.
9,572,982	B2	2/2017	Burnes et al.
9,579,484	B2	2/2017	Barnell
9,585,642	B2	3/2017	Dinsmoor et al.
9,615,832	B2	4/2017	Bose et al.
9,615,951	B2	4/2017	Bennett et al.
9,622,753	B2	4/2017	Cox
9,636,115	B2	5/2017	Henry et al.
9,636,439	B2	5/2017	Chu et al.
9,642,675	B2	5/2017	Werneth et al.
9,655,633	B2	5/2017	Leynov et al.
9,655,645	B2	5/2017	Staunton
9,655,989	B2	5/2017	Cruise et al.
9,662,129	B2	5/2017	Galdonik et al.
9,662,238	B2	5/2017	Dwork et al.
9,662,425	B2	5/2017	Lilja et al.
9,668,898	B2	6/2017	Wong
9,675,477	B2	6/2017	Thompson
9,675,782	B2	6/2017	Connolly
9,676,022	B2	6/2017	Ensign
9,692,557	B2	6/2017	Murphy
9,693,852	B2	7/2017	Lam et al.
9,700,262	B2	7/2017	Janik et al.
9,700,399	B2	7/2017	Acosta-Acevedo
9,717,421	B2	8/2017	Griswold et al.
9,717,500	B2	8/2017	Tieu et al.
9,717,502	B2	8/2017	Teoh et al.
9,724,103	B2	8/2017	Cruise et al.
9,724,526	B2	8/2017	Strother et al.
9,750,565	B2	9/2017	Bloom et al.
9,757,260	B2	9/2017	Greenan
9,764,111	B2	9/2017	Gulachenski
9,770,251	B2	9/2017	Bowman et al.
9,770,577	B2	9/2017	Li
9,775,621	B2	10/2017	Tompkins et al.
9,775,706	B2	10/2017	Peterson et al.
9,775,732	B2	10/2017	Khenansho
9,788,800	B2	10/2017	Mayoras, Jr.
9,795,391	B2	10/2017	Saatchi et al.
9,801,980	B2	10/2017	Karino et al.
9,808,599	B2	11/2017	Bowman et al.
9,833,252	B2	12/2017	Sepetka et al.
9,833,604	B2	12/2017	Lam et al.
9,833,625	B2	12/2017	Waldhauser et al.
2002/0072712	A1	6/2002	Nool et al.
2003/0078473	A1	4/2003	Richardson
2005/0085746	A1 *	4/2005	Adams A61M 25/0662 600/585
2006/0064151	A1	3/2006	Guterman
2007/0021685	A1	1/2007	Oepen et al.
2008/0281350	A1	11/2008	Sepetka
2009/0018525	A1	1/2009	Waite et al.
2009/0143851	A1	6/2009	Paul, Jr.
2010/0324649	A1	12/2010	Mattsson
2011/0319917	A1 *	12/2011	Ferrera A61B 17/12118 606/159
2012/0283768	A1	11/2012	Cox et al.
2013/0253474	A1	9/2013	Farhangnia
2014/0135812	A1	5/2014	Divino et al.
2014/0200607	A1	7/2014	Sepetka et al.
2015/0081007	A1 *	3/2015	Joye A61F 2/954 623/1.11
2015/0257774	A1 *	9/2015	Galdonik A61M 25/0108 606/127
2015/0297250	A1 *	10/2015	Farhat A61F 2/966 606/200
2016/0235464	A1 *	8/2016	Fischell A61B 18/1492
2017/0007264	A1	1/2017	Cruise et al.
2017/0007265	A1	1/2017	Guo et al.
2017/0020540	A1 *	1/2017	Chou A61M 25/04
2017/0020670	A1	1/2017	Murray et al.
2017/0020700	A1	1/2017	Bienvenu et al.
2017/0027640	A1	2/2017	Kunis et al.
2017/0027692	A1	2/2017	Bonhoeffer et al.
2017/0027725	A1	2/2017	Argentine
2017/0035436	A1	2/2017	Morita
2017/0035567	A1	2/2017	Duffy
2017/0042548	A1	2/2017	Lam
2017/0049596	A1	2/2017	Schabert
2017/0071737	A1	3/2017	Kelley
2017/0072452	A1	3/2017	Monetti et al.
2017/0079671	A1	3/2017	Morero et al.
2017/0079680	A1	3/2017	Bowman
2017/0079766	A1	3/2017	Wang et al.
2017/0079767	A1	3/2017	Leon-Yip
2017/0079812	A1	3/2017	Lam et al.
2017/0079817	A1	3/2017	Sepetka et al.
2017/0079819	A1	3/2017	Pung et al.
2017/0079820	A1	3/2017	Lam et al.
2017/0086851	A1	3/2017	Wallace et al.
2017/0086996	A1	3/2017	Peterson et al.
2017/0095259	A1	4/2017	Tompkins et al.
2017/0100126	A1	4/2017	Bowman et al.
2017/0100141	A1	4/2017	Morero et al.
2017/0100143	A1	4/2017	Grandfield
2017/0100183	A1	4/2017	Iaizzo et al.
2017/0113023	A1	4/2017	Steingisser et al.
2017/0147765	A1	5/2017	Mehta
2017/0151032	A1	6/2017	Loisel
2017/0165062	A1	6/2017	Rothstein
2017/0165065	A1	6/2017	Rothstein et al.
2017/0165454	A1	6/2017	Tuohy et al.
2017/0172581	A1	6/2017	Bose et al.
2017/0172766	A1	6/2017	Vong et al.
2017/0172772	A1	6/2017	Khenansho
2017/0189033	A1	7/2017	Sepetka et al.
2017/0189035	A1	7/2017	Porter
2017/0215902	A1	8/2017	Leynov et al.
2017/0216484	A1	8/2017	Cruise et al.
2017/0224350	A1	8/2017	Shimizu et al.
2017/0224355	A1	8/2017	Bowman et al.
2017/0224467	A1	8/2017	Piccagli et al.
2017/0224511	A1	8/2017	Dwork et al.
2017/0224953	A1	8/2017	Tran et al.
2017/0231749	A1	8/2017	Perkins et al.
2017/0252064	A1	9/2017	Staunton
2017/0265983	A1	9/2017	Lam et al.
2017/0281192	A1	10/2017	Tieu et al.
2017/0281331	A1	10/2017	Perkins et al.
2017/0281344	A1	10/2017	Costello
2017/0281909	A1	10/2017	Northrop et al.
2017/0281912	A1	10/2017	Melder et al.
2017/0290593	A1	10/2017	Cruise et al.
2017/0290654	A1	10/2017	Sethna
2017/0296324	A1	10/2017	Argentine
2017/0296325	A1	10/2017	Marrocco et al.
2017/0303939	A1	10/2017	Greenhalgh et al.
2017/0303942	A1	10/2017	Greenhalgh et al.

(56) **References Cited**

U.S. PATENT DOCUMENTS

2017/0303947	A1	10/2017	Greenhalgh et al.
2017/0303948	A1	10/2017	Wallace et al.
2017/0304041	A1	10/2017	Argentine
2017/0304097	A1	10/2017	Corwin et al.
2017/0304595	A1	10/2017	Nagasrinivasa et al.
2017/0312109	A1	11/2017	Le
2017/0312484	A1	11/2017	Shipley et al.
2017/0316561	A1	11/2017	Helm et al.
2017/0319826	A1	11/2017	Bowman et al.
2017/0333228	A1	11/2017	Orth et al.
2017/0333236	A1	11/2017	Greenan
2017/0333678	A1	11/2017	Bowman et al.
2017/0340383	A1	11/2017	Bloom et al.
2017/0348014	A1	12/2017	Wallace et al.
2017/0348514	A1	12/2017	Guyon et al.

* cited by examiner

FIG. 1

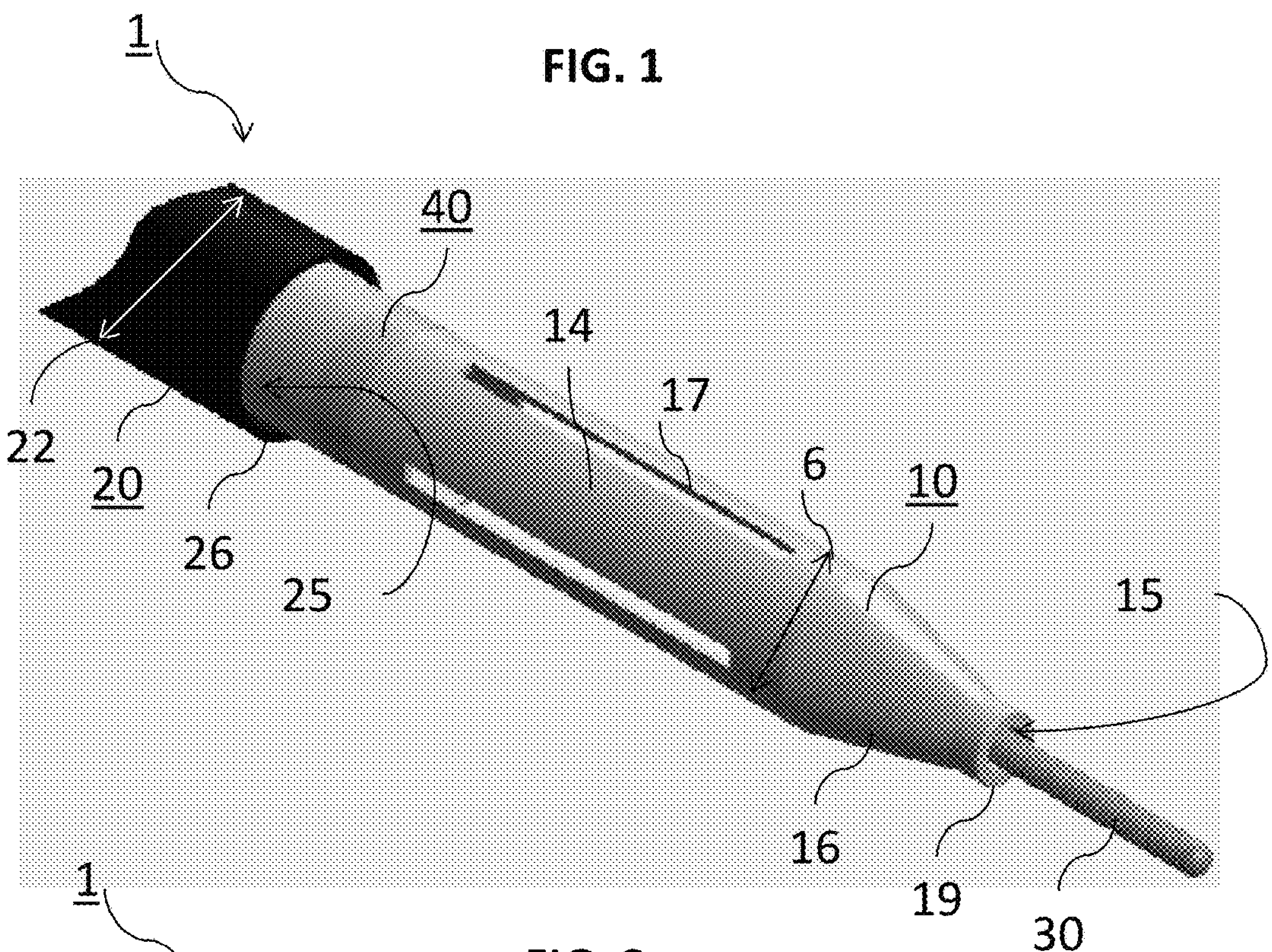


FIG. 2

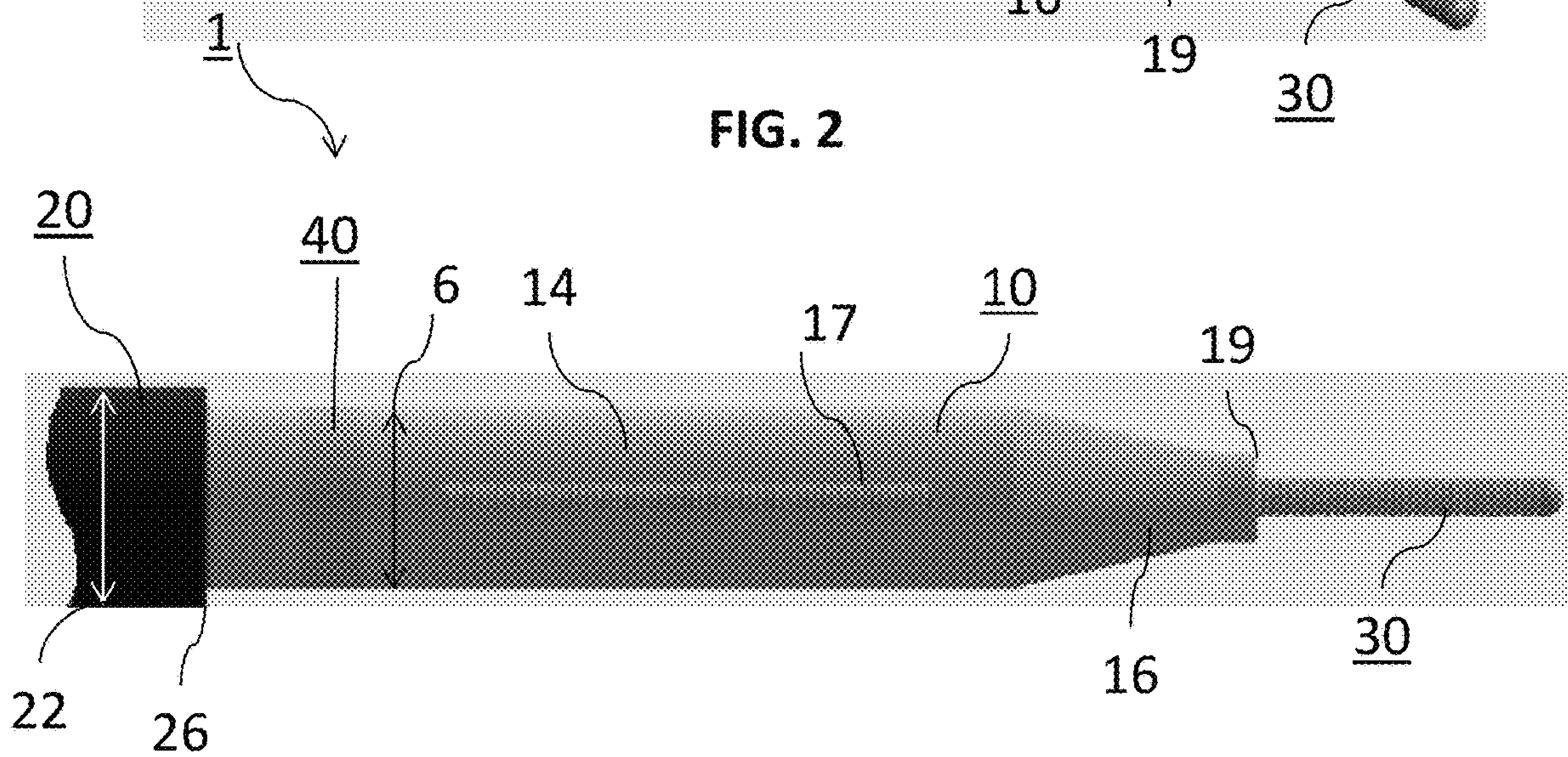


FIG. 3

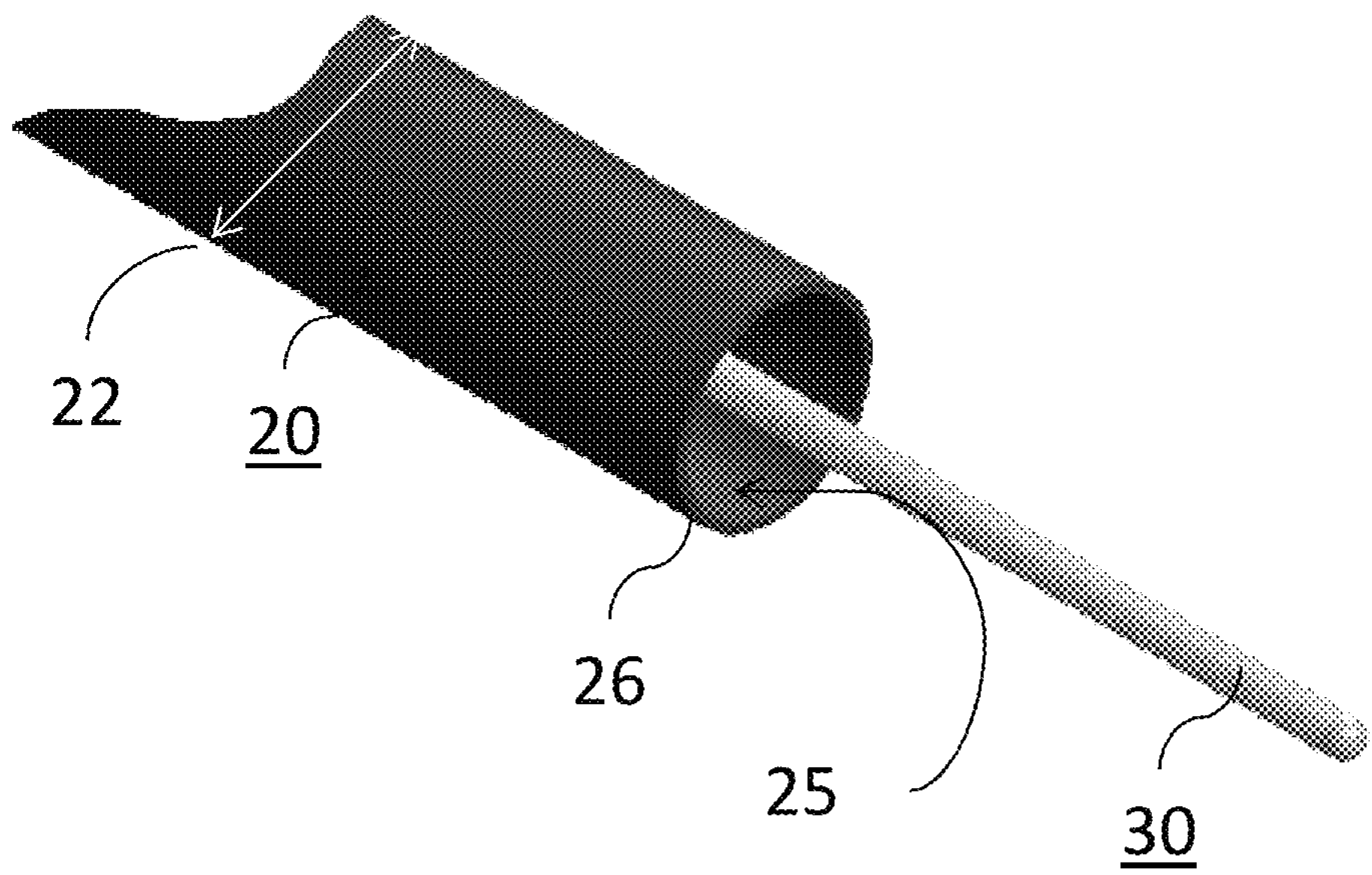


FIG. 4

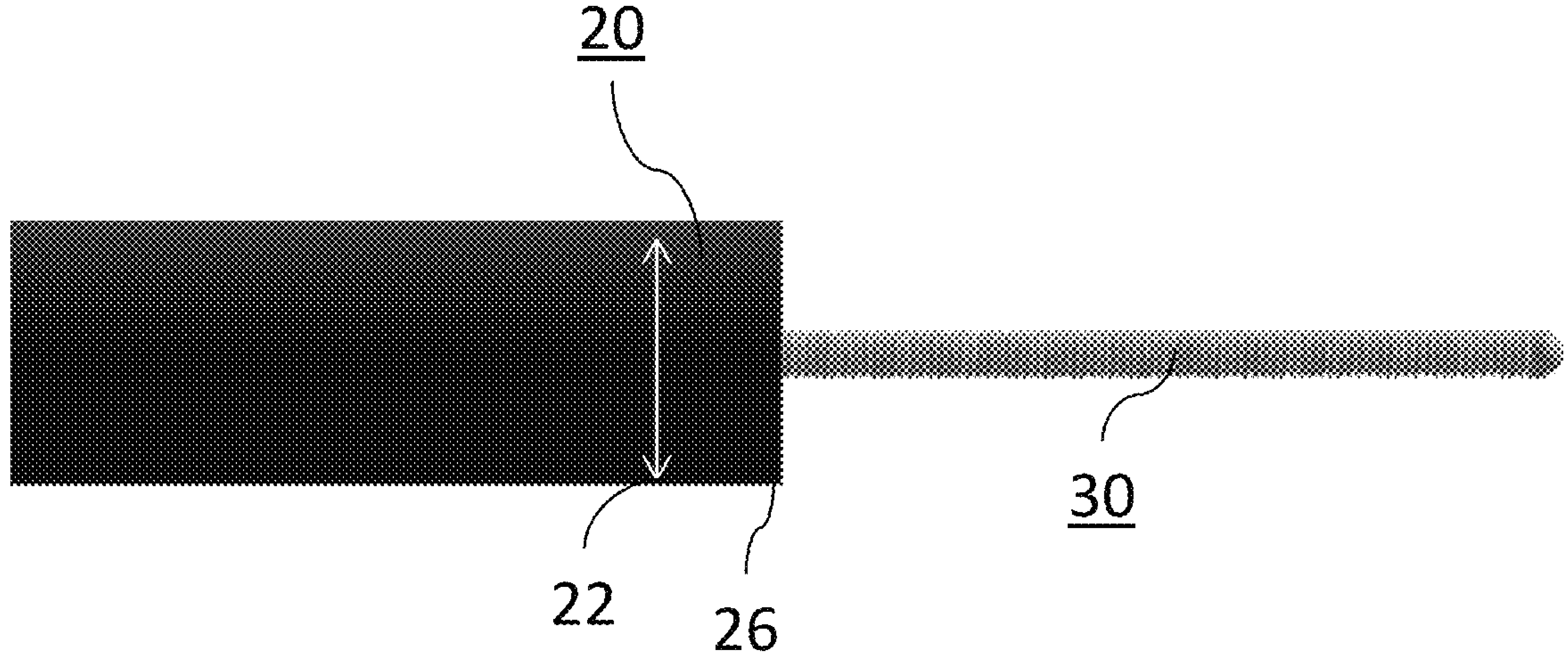


FIG. 5

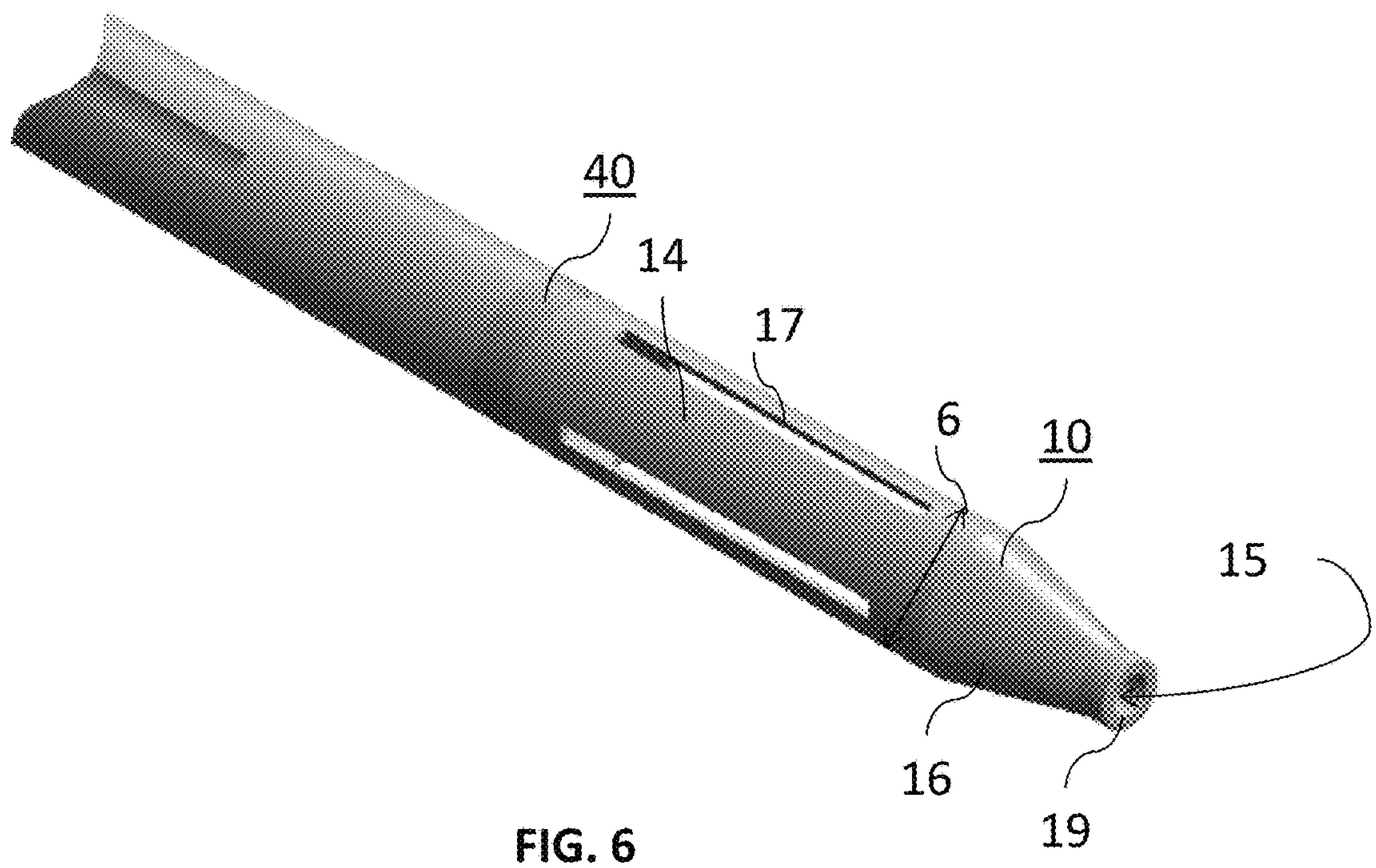


FIG. 6

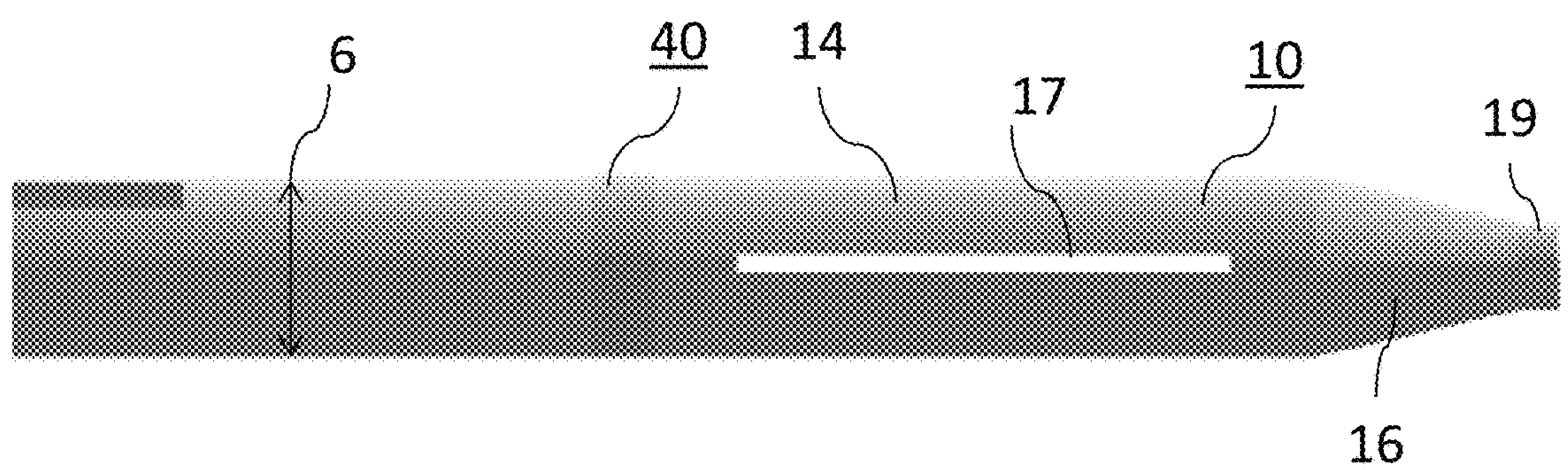


FIG. 7

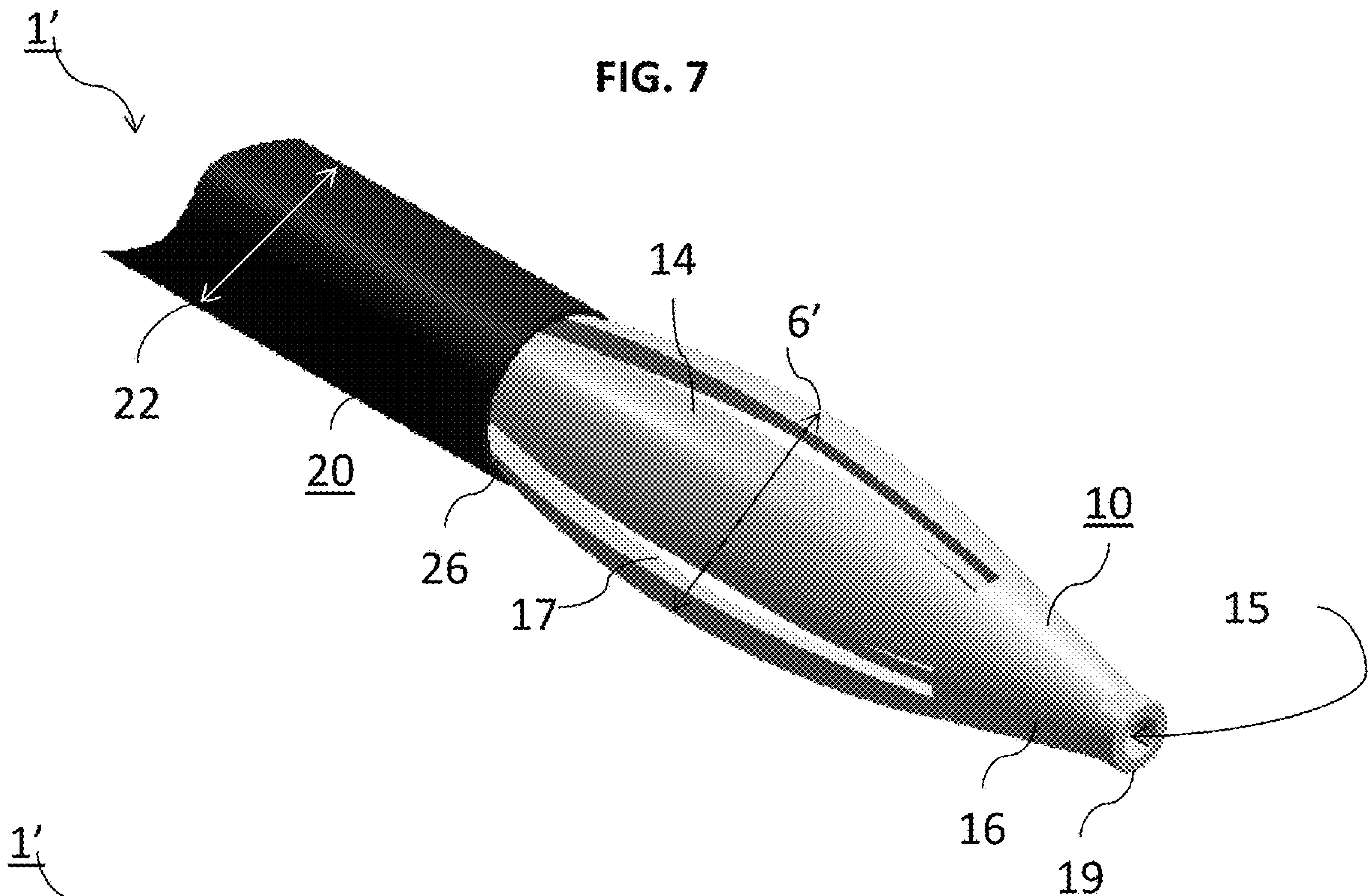


FIG. 8

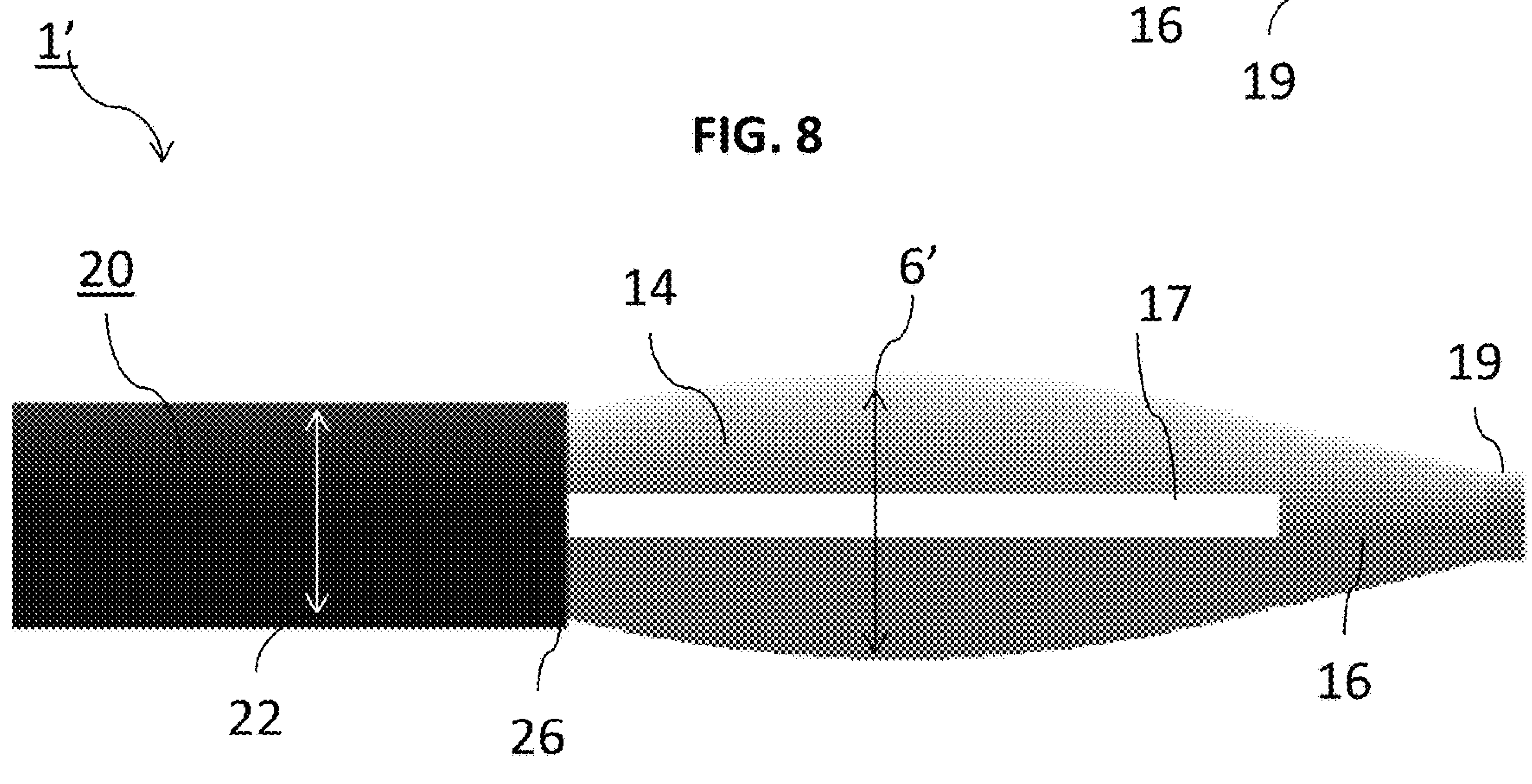


FIG. 9

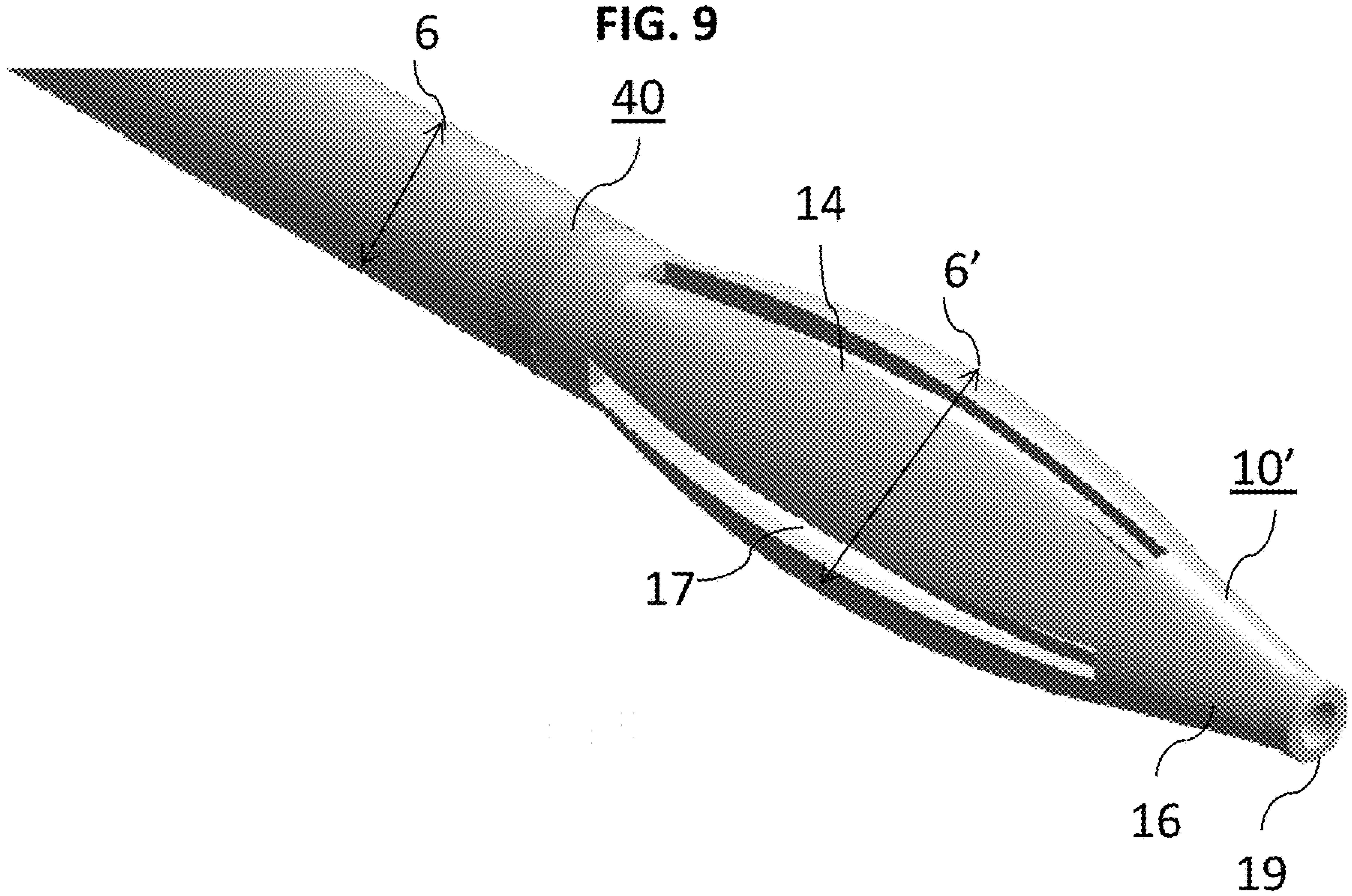


FIG. 10

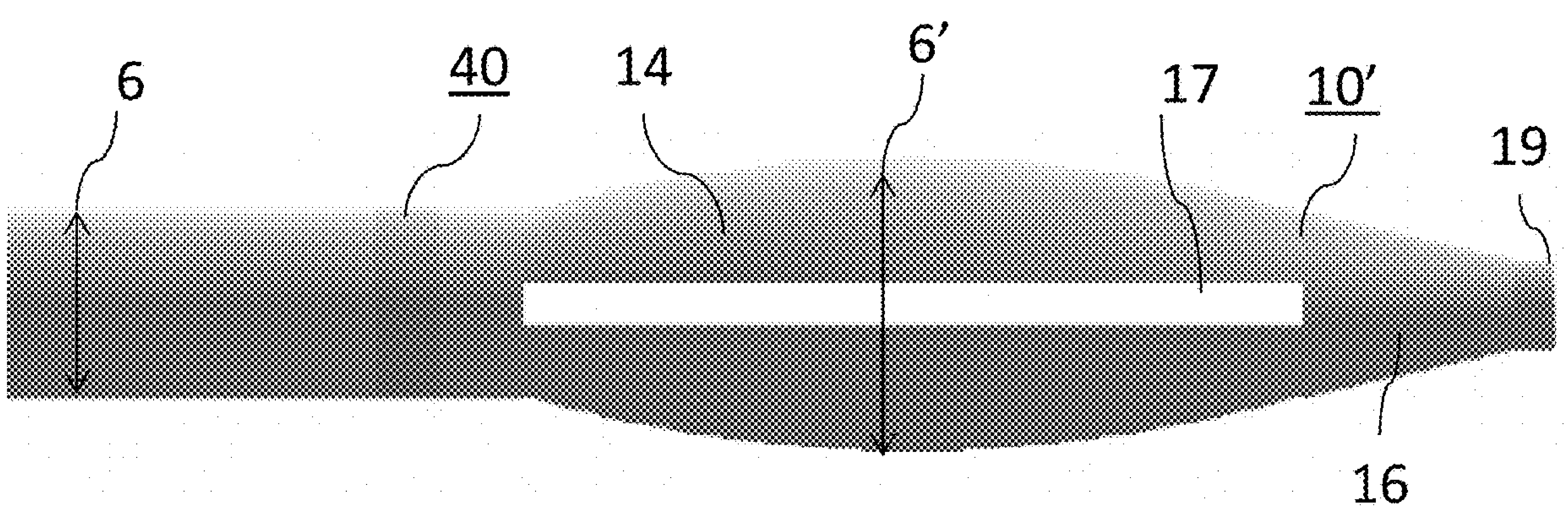


FIG. 11

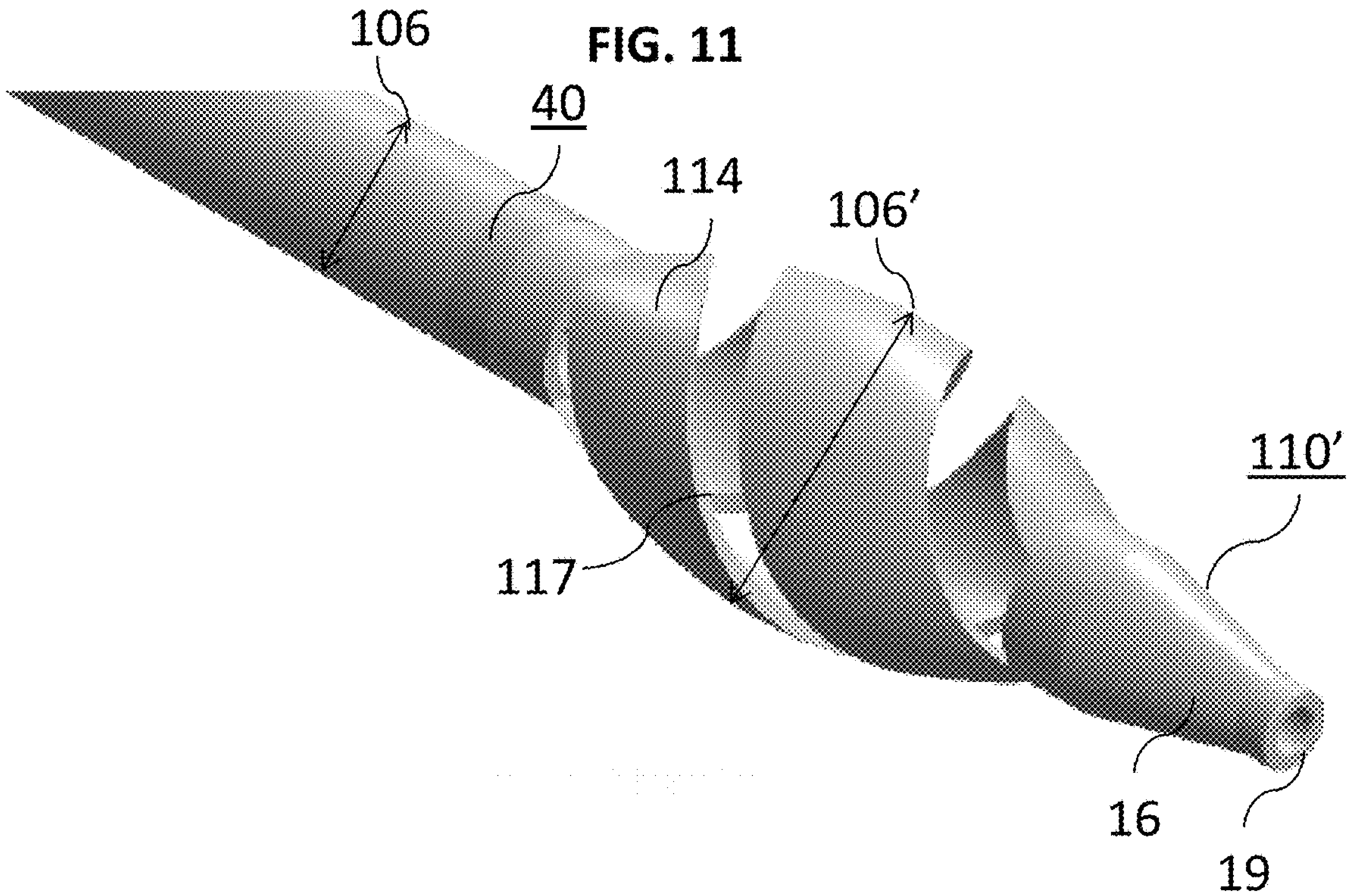


FIG. 12

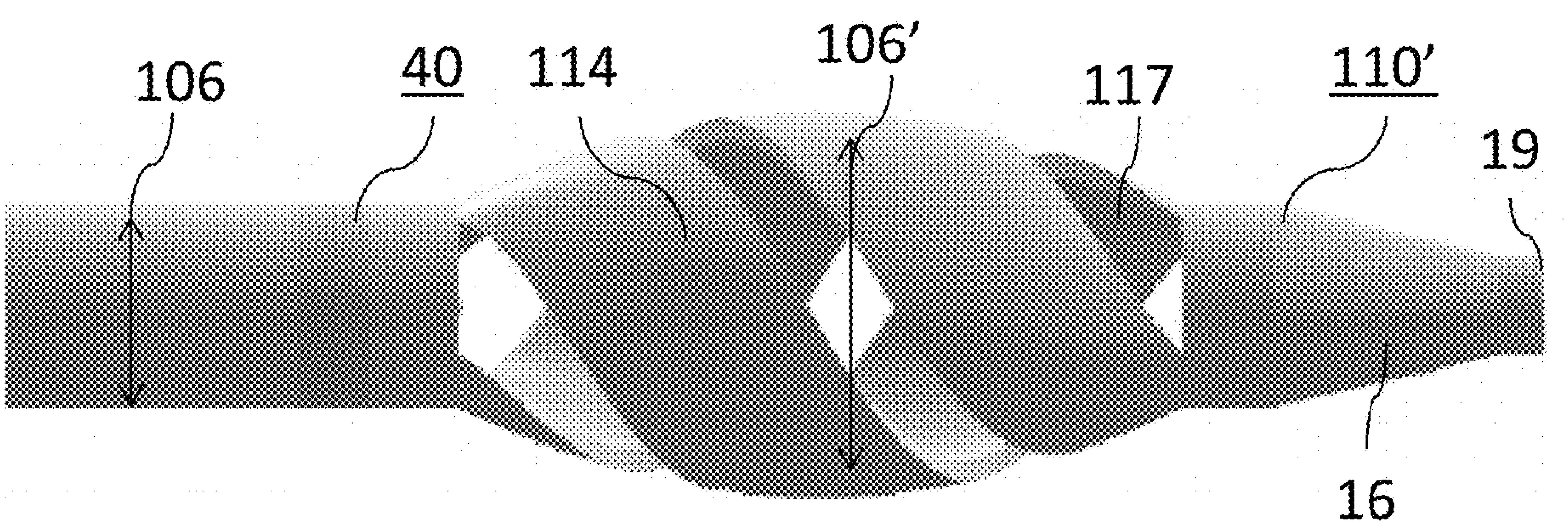


FIG. 13

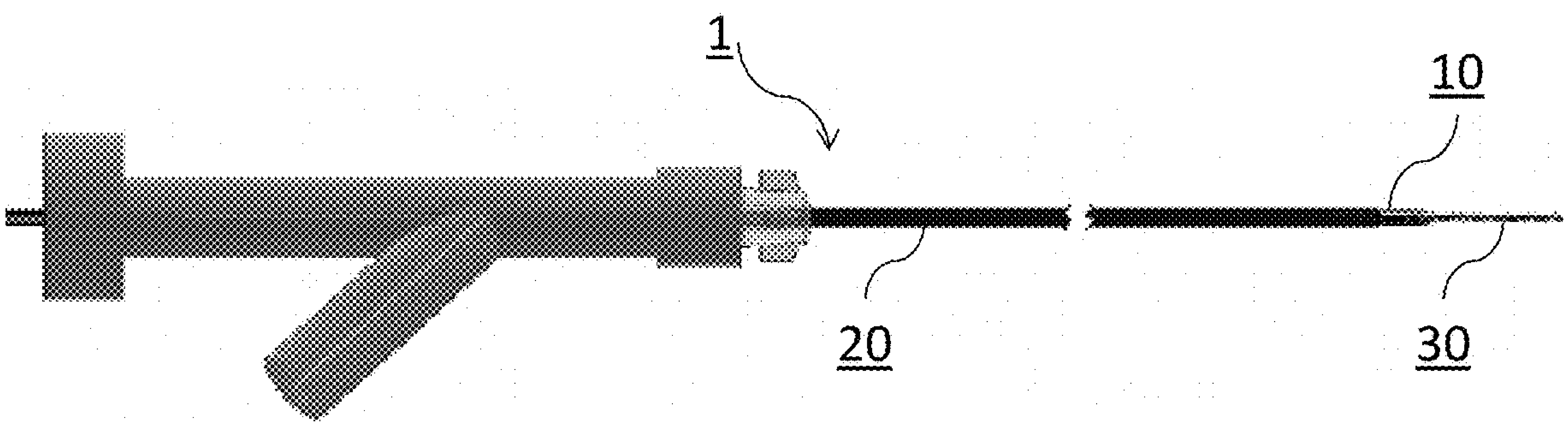


FIG. 14

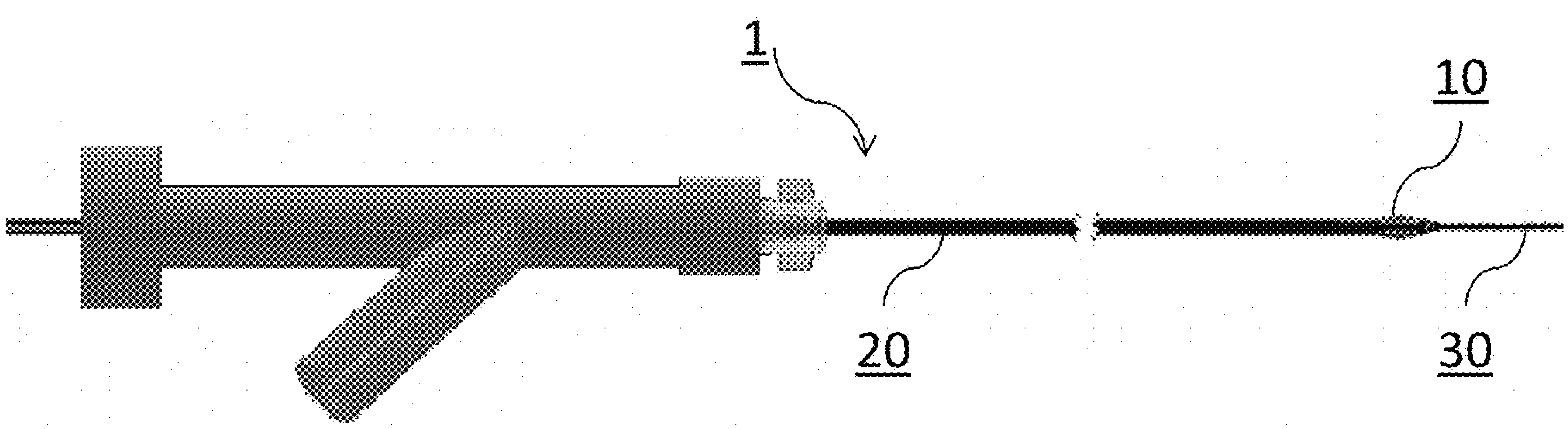


FIG. 15

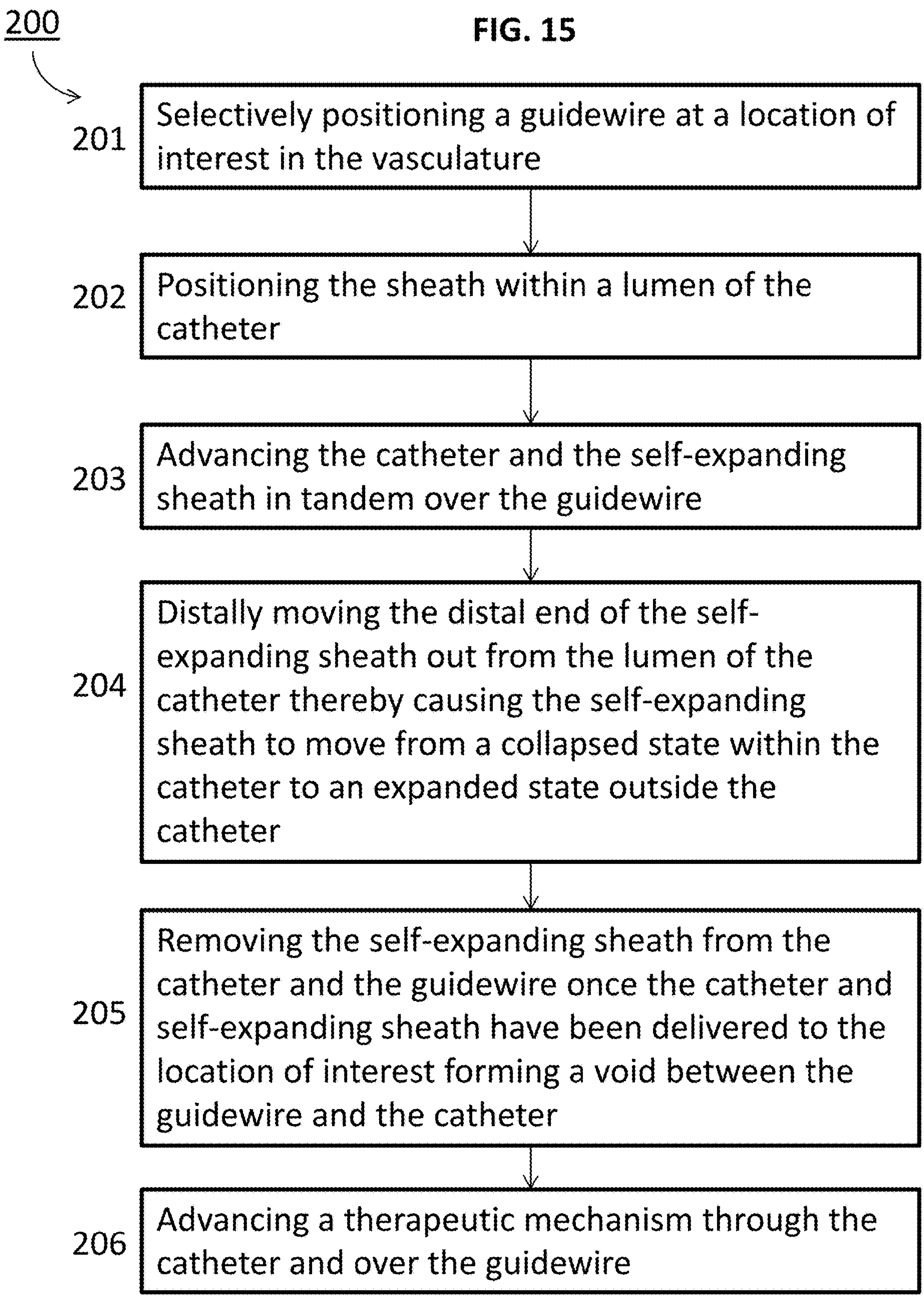
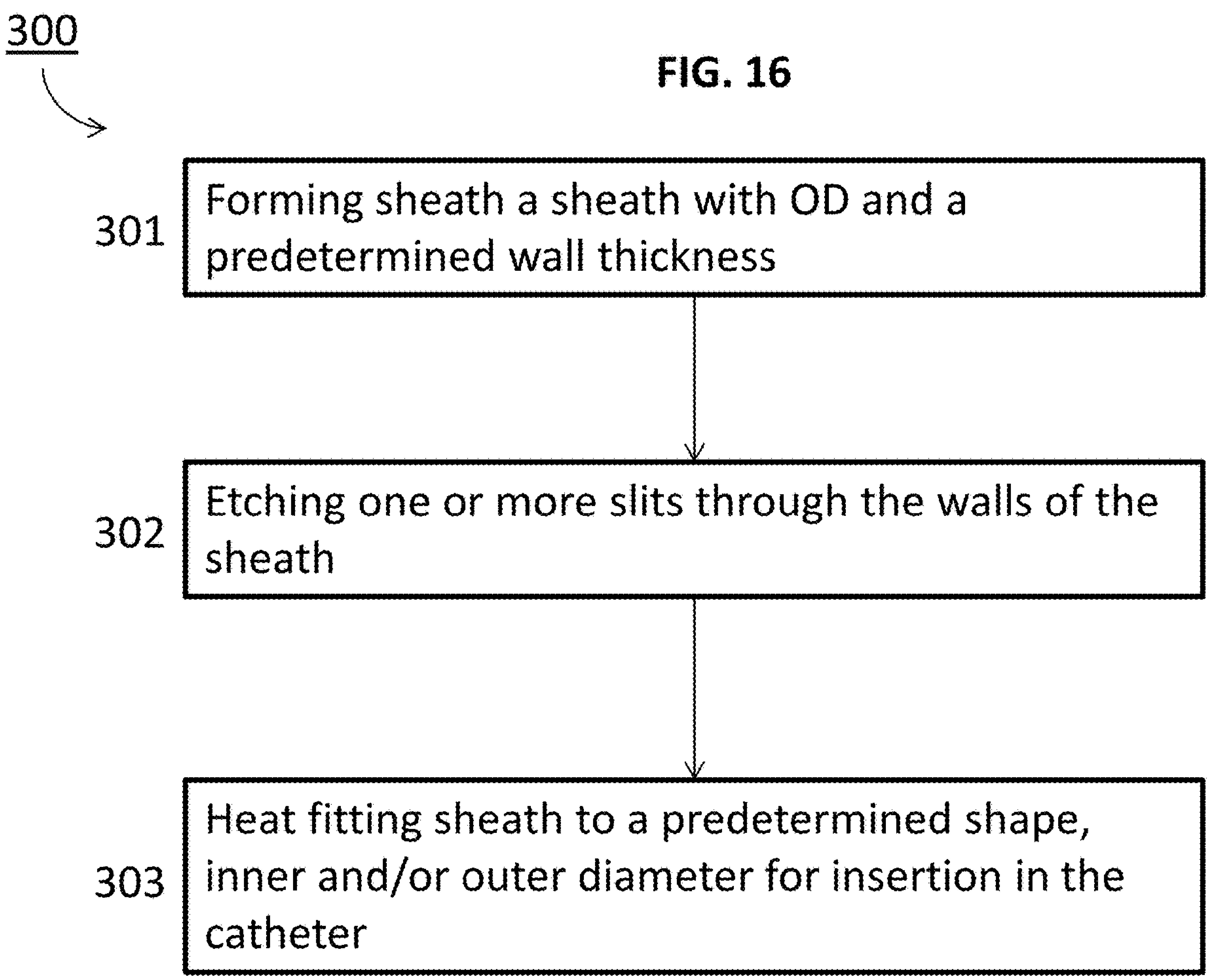

200
201
Selectively positioning a guidewire at a location of interest in the vasculature
202
Positioning the sheath within a lumen of the catheter
203
Advancing the catheter and the self-expanding sheath in tandem over the guidewire
204
Distally moving the distal end of the self-expanding sheath out from the lumen of the catheter thereby causing the self-expanding sheath to move from a collapsed state within the catheter to an expanded state outside the catheter
205
Removing the self-expanding sheath from the catheter and the guidewire once the catheter and self-expanding sheath have been delivered to the location of interest forming a void between the guidewire and the catheter
206
Advancing a therapeutic mechanism through the catheter and over the guidewire

FIG. 16


300
301
Forming sheath a sheath with OD and a predetermined wall thickness
302
Etching one or more slits through the walls of the sheath
303
Heat fitting sheath to a predetermined shape, inner and/or outer diameter for insertion in the catheter

SYSTEM AND METHOD FOR DELIVERING A CATHETER

FIELD

This disclosure relates to medical instruments, and more particularly, guidewire and catheter delivery systems.

BACKGROUND

Catheters can be pliable tubular structures that enter vasculature of a patient. Catheters can be used for a variety of purposes and applications. For example, they can be introduced into a particular area of interest within a vasculature and then act as a guide for introducing other peripheral, central venous, or arterial devices therein through its lumen. Such devices can include single or multi-lumen catheters, clot capturing devices, balloon catheters, and the like.

During certain procedures, a guidewire is typically introduced first separate from the catheter. Catheters and guidewires can range in size and diameter, depending on a particular procedure and area of interest in the vasculature. In a clinical setting, tracking of catheters over a guidewire can lead to complications since step movement between the larger catheter and smaller guidewire can lead to injuries to the vessel wall.

Additionally, previous approaches have permitted the guidewire to move within the catheter during delivery even upon the slightest pressure from the guidewire to the catheter. In turn, this risks injury to the patient. In typical guidewire-catheter systems, the guidewire is normally loose within the lumen of the catheter during delivery of the catheter and therefore susceptible to what is understood as step movement. However, because catheters can range in size depending on the therapeutic mechanisms they may deliver, larger outer diameters of the catheter unfortunately result in larger step movements between the guidewire that prevent safe delivery within the vasculature. This step movement can unnecessarily risk injuring the vessel wall or otherwise resulting in ineffective treatment.

Previous approaches, including those described in U.S. Pat. No. 7,731,707, have failed to resolve the issues related to step movement between the catheter and guidewire. For example, the '707 patent is directed towards creating a space in the vasculature itself as opposed to delivering a surface that extends beyond the outer diameter of the catheter for resolving step movement between a guidewire and catheter. Additionally, the '707 patent fails to teach or reasonably suggest any element that resolves step movement between catheter, guidewire, and vessel wall.

, Another disclosure is also seen in U.S. Pat. Pub. 2007/0021685, wherein a catheter balloon is used with a catheter. During peripheral vasculature or coronary procedures, it can be desirous for a catheter balloon to be stationary relative to the guidewire. However, in practice, because the balloon does tend to move, the '685 publication sought to resolve this movement by implementing a break inside of the balloon and by pulling on the wire at the end. In so doing, the lumen of the catheter in the '685 publication is caused to expand into a locked state. This is strictly done to avoid longitudinal movement of the balloon within the lumen, when the balloon inflates, since the balloon is then trapped in the '685 publication by the wire inside the balloon. Unfortunately, expansion and activation is only caused in the '685 publication by manually pulling on or applying tension to the wire. Additionally, in procedures that involve catheter balloons and guidewires, the guidewire must be at the location of interest first and then the balloon is tracked over the wire.

Accordingly, in the process of tracking the guidewire, a self-expanding balloon would never actually be outside the catheter or address step movement between catheter and guidewire since doing so would run counter to the specific order of operations in procedures that mirror the '685 publication. For example, if the balloon in the '685 publication did expand outside the catheter, it would be difficult to track to the catheter or to the vasculature without risking injury to the vessel walls.

Therefore, there remains a need for new devices to safely and effectively advance catheters to locations of interest when used with guidewires to resolve these and other problems of the art.

SUMMARY

In some aspects, the present disclosure relates to a catheter delivery system. The system can include a guidewire. A catheter with a lumen is also included, the catheter having a distal end and a proximal end. A self-expanding sheath may also be slidably disposed in the lumen, the self-expanding sheath having a distal end and a proximal end. The self-expanding sheath can be capable of moving from a collapsed state within the catheter to an expanded state outside the catheter during deployment with an outer diameter greater than an inner diameter of the catheter. In certain embodiments, the outer diameter of the sheath in the expanded stated may be approximately equal to or slightly larger than the outer diameter of the catheter. The self-expanding sheath and the catheter can be advanceable in tandem over the guidewire. In this respect, as the distal end of the self-expanding sheath is moved distally relative to the catheter, the self-expanding sheath expands to the expanded state.

In the collapsed state, the outer diameter of the self-expanding sheath can be substantially snug with the inner diameter of the catheter. The distal end of the self-expanding sheath can also included a convoluted tip. The tip may be tapered with the distal end including an inner diameter substantially snug with the guidewire. In certain embodiments, the guidewire and/or the inner diameter of the sheath can include a lubricant. The outer diameter of the sheath and/or the inner diameter of the catheter can also or separately include a lubricant. The self-expanding sheath can have a radiopaque band proximal to the distal end.

The self-expanding sheath may include a plurality of slits, wherein as the self-expanding sheath is moved distally away from the distal end of the catheter, the slits can cause the outer diameter of the sheath to expand so it is greater than the inner diameter of the catheter. Also, moving to the expanded state can cause the self-expanding sheath to impart an outward force to the vessel wall. In this respect, the catheter can be released from the vessel wall. The slits can be etched longitudinally and disposed between proximal and distal ends of the self-expanding sheath. The slits can also be spiral etches or curved etches disposed between proximal and distal ends of the self-expanding sheath. The slits of each embodiment can enhance flexibility of the self-expanding sheath where otherwise adding a sheath would risk rendering the catheter too rigid for use in the tortuous vessels.

In some embodiments, the self-expanding sheath may be movable so that its distal end is capable of being distal of the distal end of the distal end of the catheter. Moving the distal end of the self-expanding sheath a predetermined distance away from the distal end of the catheter can cause the outer diameter of the self-expanding sheath to be greater than the outer diameter of the catheter.

In other embodiments, a self-expanding sheath is disclosed for use with a catheter and a guidewire. The sheath can include an outer surface slidably disposable in a lumen of the catheter. An expandable element may also be disposed on a distal end of the self-expanding sheath, the expandable element capable of moving from a collapsed state within the lumen to an expanded state outside the lumen during deployment. An outer diameter of the expandable element can be greater than an outer diameter of the catheter. The self-expanding sheath may be capable of being advanced in tandem with the catheter over the guidewire such that as the distal end of the self-expanding sheath is moved distally relative to the catheter, the self-expanding sheath can deploy or move to the expanded state. The expandable element can include a plurality of slits etched between distal and proximal ends of the sheath. As the self-expanding sheath is moved distally away from the distal end of the catheter, the slits cause the outer diameter of the sheath to be greater than the inner diameter of the catheter. In the expanded state, the slits can cause the sheath to form a "pear-like" shape.

In other embodiments, a method is disclosed for delivering a catheter to a location of interest in the vasculature. The method can include selectively positioning a guidewire at the location, positioning a self-expanding sheath within a lumen of the catheter, advancing the catheter and the self-expanding sheath in tandem over the guidewire, and distally moving a distal end of the self-expanding sheath out from the lumen of the catheter thereby causing the self-expanding sheath to move from a collapsed state within the catheter to an expanded state outside the catheter.

The method can also include having an outer surface of the self-expanding sheath contact the distal end of the lumen as the sheath is deployed so that the sheath separates the catheter from the vessel walls. In certain embodiments, the method can also include forming a plurality of slits on the self-expanding sheath between its proximal and distal ends, and the slits causing the self-expanding sheath to expand to the expanded stated with an outer diameter greater than the outer diameter of the catheter. The method may also include extending the distal end of the sheath beyond a distal end of the catheter thereby smoothening a transition between the catheter and the guidewire during delivery. The method can also include removing the self-expanding sheath from the catheter and the guidewire once the catheter and self-expanding sheath have been delivered to the location of interest forming a void between the guidewire and the catheter. Finally, the method can include the self-expanding sheath imparting an outward expansion force to the vessel wall as the self-expanding sheath moves to the expanded state.

Other aspects and features of the present disclosure will become apparent to those of ordinary skill in the art, upon reviewing the following detailed description in conjunction with the accompanying figures.

BRIEF DESCRIPTION OF THE DRAWINGS

Reference will now be made to the accompanying drawings, which are not necessarily drawn to scale.

FIG. **1** is a partial perspective view of an example embodiment of the catheter system disclosed herein, wherein the sheath is being deployed from the catheter.

FIG. **2** is a partial side plan view of the system shown in FIG. **1**.

FIG. **3** is a partial perspective view of the catheter and guidewire of FIGS. **1-2** without the sheath.

FIG. **4** is a partial side plan view of the catheter and guidewire of FIGS. **1-2** without the sheath.

FIG. **5** is a partial perspective view of a sheath in a collapsed state.

FIG. **6** is a side plan perspective view of a sheath in a collapsed state.

FIG. **7** is a partial perspective view the catheter system disclosed herein, wherein the sheath is deployed from the catheter in an expanded state.

FIG. **8** is a partial side plan view of the system shown in FIG. **7**.

FIG. **9** is a partial perspective view of a sheath in an expanded state.

FIG. **10** is a side plan perspective view of the sheath in FIG. **9**.

FIG. **11** is a partial perspective view of another exemplary sheath in an expanded state.

FIG. **12** is a side plan perspective view of the sheath in FIG. **11**.

FIG. **13** is a side plan view of an example embodiment of the catheter system disclosed herein in combination with an exemplary delivery system, wherein the sheath and catheter are compressed.

FIG. **14** is a side plan view of an example embodiment of the catheter system disclosed herein in combination with an exemplary delivery system, wherein the sheath and catheter are in an expanded state.

FIG. **15** is a flow diagram for a method of delivering a catheter to a location of interest in the vasculature.

FIG. **16** is a flow diagram for a method of manufacturing a self-expanding sheath.

DETAILED DESCRIPTION

Although example embodiments of the disclosed technology are explained in detail herein, it is to be understood that other embodiments are contemplated. Accordingly, it is not intended that the disclosed technology be limited in its scope to the details of construction and arrangement of components set forth in the following description or illustrated in the drawings. The disclosed technology is capable of other embodiments and of being practiced or carried out in various ways.

It must also be noted that, as used in the specification and the appended claims, the singular forms "a," "an" and "the" include plural referents unless the context clearly dictates otherwise. By "comprising" or "containing" or "including" it is meant that at least the named compound, element, particle, or method step is present in the composition or article or method, but does not exclude the presence of other compounds, materials, particles, method steps, even if the other such compounds, material, particles, method steps have the same function as what is named.

In describing example embodiments, terminology will be resorted to for the sake of clarity. It is intended that each term contemplates its broadest meaning as understood by those skilled in the art and includes all technical equivalents that operate in a similar manner to accomplish a similar purpose. It is also to be understood that the mention of one or more steps of a method does not preclude the presence of additional method steps or intervening method steps between those steps expressly identified. Steps of a method may be performed in a different order than those described herein without departing from the scope of the disclosed technology. Similarly, it is also to be understood that the mention of one or more components in a device or system does not preclude the presence of additional components or intervening components between those components expressly identified.

As discussed herein, vasculature of a "subject" or "patient" may be vasculature of a human or any animal. It should be appreciated that an animal may be a variety of any applicable type, including, but not limited thereto, mammal, veterinarian animal, livestock animal or pet type animal, etc. As an example, the animal may be a laboratory animal specifically selected to have certain characteristics similar to a human (e.g., rat, dog, pig, monkey, or the like). It should be appreciated that the subject may be any applicable human patient, for example.

As discussed herein, "operator" may include a doctor, surgeon, or any other individual or delivery instrumentation associated with delivery of a braided stent body to the vasculature of a subject.

The method and systems disclosed herein are directed towards minimizing or eliminating the step between a catheter and corresponding guidewire and to form a backward step. A guidewire can be selectively positioned at a location of interest in the vasculature. A self-expanding sheath may be assembled with a catheter by being slidably inserted therein, wherein the catheter and self-expanding sheath can then be advanced in tandem over a guidewire. The self-expanding sheath may not completely hug or contact the guidewire. While the sheath can be collapsed within the catheter, the sheath may be self-expanding so that an outer surface of the sheath can be larger than the outer surface of the catheter during deployment. In this respect, once the sheath and catheter have been positioned at the location of interest in the vasculature, the sheath can be moved distal so that it extends beyond the outer diameter (OD) of the catheter. As the sheath is deployed, it expands so that the sheath operates to separate the catheter from the vessel walls during use.

The herein disclosed system and method that incorporates the self-expanding sheath, catheter, and guidewire may be delivered to the location of interest without any corresponding therapeutic mechanisms (e.g. a balloon, coil, adhesive, or the like). Instead, the system and method disclosed herein is a safe, efficient, and cost-effective solution for delivering a catheter in tandem with a sheath disposed therein, wherein the sheath can be moved distally out from the inner lumen of the catheter so that the guidewire can safely deliver therapeutic mechanisms to the location of interest. In particular regard to procedures in the neurovasculature, vessels are typically tortuous through which catheters can be difficult to advance. By using the self-expanding sheath of this disclosure, the catheter can be safely traversed within the vasculature, tortuous or not, since the step movement is minimized between the catheter and guidewire.

Turning to FIGS. **1-2**, one embodiment of the self-expanding sheath **10** is depicted assembled with the catheter **20** and guidewire **30** extended therethrough. The sheath **10** includes a proximal end **18** near the operator, and a distal end **19** disposed away from the operator. At a distal end **26** of the catheter **20** where the guidewire **30** can be caused to be deployed, the sheath **10** may be in contact at its outer surface with the inner surface of the catheter **20** at its distal end **26** as the sheath **10** expands during deployment. This is particularly advantageous in the art as catheter flexibility is necessary for tracking and maintaining patient safety during use. While adding a sheath to a guidewire-catheter system would normally surrender flexibility of the catheter when the sheath is stowed therein, the self-expanding, flexible sheath **10** described herein permits the sheath and catheter to be collectively flexible and trackable during use over the guidewire **30** within the vasculature.

The sheath **10** and the catheter **20** may be advanced in tandem over the guidewire **30** simultaneously to the location of interest (as opposed to tracking a self-expanding balloon first and then the catheter). After catheter **20** and self-expanding sheath **10** are advanced to the location of interest, the sheath **10** can then be advanced distally away from the catheter **20** a predetermine distance so that it self-expands a predetermined amount OD at the distal end of the catheter **20** that is greater than the OD of the catheter. In turn, any step movement between the guidewire **30** and catheter **20** is all but eliminated when the catheter **20** is being advanced thereover to the location of interest. The sheath **10** described herein can be used over the guidewire **30** so as to minimize the step between OD of the guidewire **30** and ID of the catheter **20** to facilitate safe insertion of a venous device into vasculature of a patient.

The snug fit between sheath **10**, catheter **20**, and guidewire **30** ensures that the guidewire **30** does not otherwise injure the patient. Specifically, system and methods of this disclosure are directed towards different procedures altogether without catheter balloons. In the system and methods of this disclosure, catheter **20** may be any biocompatible material known, including a polymeric material such as polyethylene, polypropylene, polystyrene, polyester, polyurethane, polyamide, peboxes, and the like. For example, the catheter **20** can be formed from a rubber or a plastic such as fluorinated ethylene-propethylene (FEP), polyethylene (PE), or the like. Catheter **20** can be elongate and/or tubular with an inner lumen **25** that extends longitudinally through catheter **20**. Catheter **20** can have an OD **22** and an ID **24** defined by lumen **25**.

The self-expanding sheath **10** may have an inner lumen **12**, wherein the sheath **10** can have an OD **6** and an ID **8**. Sheath **10** may be may be any biocompatible material known, including a polymeric material such as polyethylene, polypropylene, polystyrene, polyester, polyurethane, polyamide, peboxes, and the like. Sheath **10** may be capable of extending internally along catheter **20**. A distal end **19** of sheath **10** may extend beyond a distal end **24** of catheter **20** thereby avoiding a blunt transition between catheter **20** and guidewire **30**. It is understood that sheath **10** may be movable within catheter **20**, fixed in place, or movable between a plurality of predetermined positions.

The OD **6** of sheath **10** can be disposed inside catheter **20** before or while catheter is disposed in the vasculature of the patient. The OD **6** of the sheath **10** may be configured to fit snugly within the catheter **20** so as to minimize the step or distance between the sheath **10** and catheter **20**. In some embodiments, the OD **6** of sheath **10** may be substantially similar to the ID **22** of catheter **20**. Sheath **10** may also be partially or substantially covered with a lubricant coating or be constructed from a material that induces movement between sheath **10** and catheter **20**.

Sheath **10** may also include a radio opaque portion **40**. Portion **40** may be one or more bands or selected areas of sheath **10** constructed from a radio opaque material. Portion **40** can be disposed about sheath **10** to facilitate the fluoroscopic observation thereof during a procedure. Another radiopaque marker can be provided on catheter **20** to fluoroscopically determine the location of guidewire **30** and/or catheter **20**. Guidewire **30** may be any guidewire as is known in the art, including being elongated, constructed of any relatively rigid material including metals. Guidewire **30** may be any shape and may have a constant stiffness or flex.

Sheath **10** may be formed from one material or from a blend of materials selectively positioned for operable for positioning within catheter **20** when disposed in the vasculature of a patient. In certain embodiments, sheath **10** can be formed from a material that becomes softer with warmer temperatures but is substantially rigid outside the patient. Typical materials can include polyurethane, polytetrafluorethylene (PTFE), FEP, or PE.

Once the catheter **20** and self-expanding sheath **10** have been delivered to the location of interest, the self-expanding sheath **10** may be removed from the catheter and the patient thereby leaving a space between the guidewire and catheter to carry out the required procedure and deliver therapeutic mechanisms thereto. This can be more clearly seen in FIGS. **3** and **4**, wherein a partial perspective view of system **1** is shown whereby sheath **10** has been removed leaving only guidewire **30** and catheter **20**. This space that is defined between the guidewire **30** and ID **24** of catheter **20** can accommodate various therapeutic mechanisms that may be desired for delivery to the location of interest for the relevant procedure. Thus, in one example, the self-expanding sheath **10** cannot and does not provide or deliver any therapeutic mechanisms to the patient. It can be solely used to deliver the catheter **20** along the guidewire **30** to the location of interest.

A convoluted tip **16** can be located at the distal end **19** of sheath **10**. In FIGS. **1-2**, tip **16** can be seen as tapering from OD **6** to a smaller diameter at its distal end **19** about guidewire **30**. This is more clearly seen in FIGS. **5-6** which show sheath **10** alone, unassembled with catheter **20** and guidewire **30**. Specifically, FIG. **5** depicts a partial perspective view of sheath **10** and FIG. **6** depicts a partial side plan view of sheath **10**. Tip **16** is disposed adjacent sidewalls **14** which may be substantially non-convoluted or tubular along the ID **22** of catheter **20**. Sidewalls **14** can be circular or tubular but sheath **10** is not so limited and may be any shape, including oblong shapes, depending on the corresponding catheter **20**. Sidewalls **14** include one or more slits **17** or cutouts. The one or more slits **17** can extend partially or completely through sidewalls **14** and may weaken the structural integrity of sheath **10**. In this regard, flexibility of sheath **10** is enhanced. Slits **17** can extend partially and/or completely axially along the OD **6** and ID **8** of sheath **10**. Tip **16** can include an opening **15** operable to slide over guidewire **30**. Step movement is substantially limited, if not eliminated, as between opening **15** of the distal end **19** of sheath **10** and guidewire **30** since the ID of opening **15** of sheath **10** is slightly larger than the OD of the guidewire **30**. In certain embodiments, a gap of about 0.0002"-0.001" can exist between guidewire **30** and the ID of the opening of the sheath **10** thereby permitting the guidewire **30** to move independently of the sheath **10**.

Slits **17** may be self-expanding and etched longitudinally between distal and proximal ends of the sheath **10**. The slits **17** may be integrally formed with the sheath **10**. The sheath **10** may also be constructed from a single, unitary material. In certain embodiments, the sheath **10** with its one or more slits **17** may impart a predetermined outward force to the vessel wall as it expands when being slid distally out of the catheter **20** during use. In certain embodiments, the slits **17** may be formed with the sheath **10** so that the sheath **10** in a deployed, expanded state takes a "pear-like" shape. However, sheath **10** is not so limited and the sheath **10** may take any shape as needed or required in an expanded state that can expand the vasculature to move catheter **20** from contacting the vessel walls. Longitudinal slits **17** are particularly advantageous from a manufacturing and design perspective since they minimize complexity without sacrificing the self-expanding nature of the sheath when used in a system with a catheter and guidewire.

In FIGS. **7-8**, system **1** is depicted with sheath **10** having been moved distally away from catheter into the expanded state. FIG. **7** in particular depicts a perspective view of sheath **10** in an expanded state and assembled with guidewire **30** and catheter **20**. FIG. **8** depicts a side plan view of the system **1** shown in FIG. **7**. Sheath **10** may be operable to move between a compressed state within the catheter **20** and a deployed state outside of the catheter **20**. OD **6'** of the sheath **10** in the deployed state may be a predetermined ratio greater than the OD **22** of the catheter **20**. However, in the deployed state, the sheath **10** does not exhibit outward pressure such as, for example, a catheter balloon that imparts pressures to vessel walls of the vasculature.

Turning to FIGS. **9-10**, sheath **10'** is depicted alone in an expanded state unassembled with catheter **20** and guidewire **30**. Specifically, FIG. **9** depicts a partial perspective view of sheath **10'** and FIG. **10** depicts a partial side plan view of sheath **10'**. Sidewalls **14** expand as slits **17** are moved distally away from catheter **20** thereby causing its OD **6** to expand to expanded OD **6'**. In the expanded state, as shown, sheath **10'** may take a "pear-like", elliptical shape with its central portion having an OD substantially greater than the OD associated with distal end **19** and/or portion **40**. However, sheath **10'** is not so limited and sheath **10'** may take any shape or assume any OD that is at least greater than OD **22** of catheter **20** so that sheath **10'** is capable of imparting an outward force to the vessel walls during deployment from catheter **20**.

Turning to FIGS. **11-12**, another sheath **110'** is depicted alone in an expanded state unassembled with catheter **20** and guidewire **30**. Specifically, FIG. **11** depicts a partial perspective view of sheath **110'** and FIG. **12** depicts a partial side plan view of sheath **110'**. Instead of being longitudinally etched, slits **117** may be spiral or curved slits etched into sidewalls **114** of sheath **110'**. As a result, sidewalls **114** expand as slits **117** are moved distally away from catheter **20** thereby causing its OD **6** to expand to expanded OD **6'**. In the expanded state, as shown, sheath **110'** may take a "pear-like", elliptical shape with its central portion having an OD substantially greater than the OD associated with distal end **119** and/or portion **40**. However, sheath **110** is not so limited and sheath **110'** may take any shape or assume any OD that is at least greater than OD **22** of catheter **20** so that sheath **110'** is capable of imparting an outward force to the vessel walls during deployment from catheter **20**.

Turning to FIGS. **13** and **14** are side plan views of an example catheter system **1** in combination with an exemplary delivery system, wherein the sheath **10** and catheter **20** in FIG. **13** are compressed but in the process of being deployed. FIG. **14** shows the sheath **10** and catheter **20** in an expanded state following deployment from the delivery system.

Turning to FIG. **15** is a method **200** of delivering catheter **20** to a location of interest in the vasculature. The method can include (**201**) selectively positioning guidewire **30** at the location, (**202**) positioning sheath **10** within a lumen of the catheter **20**, (**203**) advancing the catheter **20** and the self-expanding sheath **10** in tandem over the guidewire **30**, and (**204**) distally moving distal end **19** of the self-expanding sheath **10** out from the lumen of the catheter **20** thereby causing the self-expanding sheath **10** to move from a collapsed state within the catheter **20** to an expanded state outside the catheter **20**. The method can also include (**205**) removing the self-expanding sheath **10** from the catheter **20** and the guidewire **30** once the catheter **20** and self-expanding sheath **10** have been delivered to the location of interest forming a void between the guidewire **30** and the catheter **20**. The method can also include (**206**) advancing a therapeutic mechanism through the catheter **20** and over the guidewire **30**.

Turning to FIG. **16**, a method **300** is disclosed for manufacturing sheath **10**, **110** for use in a system **1** with guidewire **30** and catheter **20**. The method may include step **301** wherein sheath **10**, **110** is formed with OD **6**, **106** and a predetermined wall thickness. Then, in step **302** one or more slits **17**, **117** can be etched through the walls of the sheath **10**, **110**. In step **303**, sheath **10**, **110** may be heat fit to a predetermined shape, inner and/or outer diameter for insertion in the catheter **20**. Sheath **10**, **110** may have a predetermined resiliency and/or flexibility. During use, sheath **10**, **110** and catheter **20** may be advanced in tandem over guidewire **30** to a location of interest in the vasculature, wherein sheath **10**, **110** can be moved distally passed distal end **26** of catheter **20** thereby causing sheath **10**, **110** to move from a first OD **6**, **106** and second, greater OD **6'**, **106'** that is larger than OD **22** of catheter **20**.

The systems and methods of this disclosure also contemplate a catheter system **500** that may be a kit that includes catheter **20** and one or more of sheaths **10**, **110**. Each sheath **10**, **110** can be separately, selectively inserted within catheter **20**. Each sheath **10**, **110** can range in terms of diameter and/or any of the previously disclosed shapes. A kit may include a plurality of sheathes (e.g. 10 sheathes) that are separately sized so that a given sheath can be selected and positioned as required for different sized guidewires.

The specific configurations, choice of materials and the size and shape of various elements can be varied according to particular design specifications or constraints requiring a system or method constructed according to the principles of the disclosed technology. Such changes are intended to be embraced within the scope of the disclosed technology. The presently disclosed embodiments, therefore, are considered in all respects to be illustrative and not restrictive. It will therefore be apparent from the foregoing that while particular forms of the disclosure have been illustrated and described, various modifications can be made without departing from the spirit and scope of the disclosure and all changes that come within the meaning and range of equivalents thereof are intended to be embraced therein.

What is claimed is:

1. A catheter delivery system, comprising:

a guidewire;

a catheter comprising a lumen, a distal end, and a proximal end;

a polymeric self-expanding sheath slidably disposed in the lumen, the self-expanding sheath comprising:

a distal end;

a proximal end;

a distal portion approximate the distal end of the sheath; and

a self-expanding sidewall in the distal portion comprising slits therein to define segments of the self-expanding sidewall each having a respective arcuate cross section in a plane orthogonal to a longitudinal axis of the sheath in an expanded state, the self-expanding sidewall being capable of moving from a collapsed state within the catheter to the expanded state outside the catheter during deployment with an outer diameter greater than an outer diameter of the catheter;

wherein the self-expanding sheath and the catheter are advanceable in tandem over the guidewire such that as

the distal end of the self-expanding sheath is moved distally relative to the catheter, the self-expanding sidewall expands to the expanded state, and

wherein the self-expanding sheath is removable from the lumen via the proximal end of the catheter.

2. The system of claim **1**, wherein in the collapsed state, the outer diameter of the self-expanding sidewall is substantially snug with an inner diameter of the catheter.

3. The system of claim **1**, wherein the distal end of the self-expanding sheath comprises a tapered tip comprising a diameter smaller than a diameter of the distal portion, the distal end comprising an inner diameter substantially snug with the guidewire.

4. The system of claim **3**, wherein at least one of the guidewire, an inner diameter of the sheath, the outer diameter of the sheath, and the inner diameter of the catheter includes a lubricant.

5. The system of claim **1**, wherein the self-expanding sheath comprises a radiopaque band proximal to the distal end.

6. The system of claim **1**, wherein the self-expanding sheath is movable so that its distal end is capable of being distal of the distal end of the catheter.

7. The system of claim **6**, wherein moving the distal end of the self-expanding sheath a predetermined distance away from the distal end of the catheter causes the outer diameter of the self-expanding sidewall to be greater than the outer diameter of the catheter.

8. A catheter delivery system, comprising:

a guidewire;

a catheter comprising a lumen, a distal end, and a proximal end;

a polymeric self-expanding sheath slidably disposed in the lumen, the self-expanding sheath comprising:

a distal end;

a proximal end;

a distal portion approximate the distal end of the sheath; and

a self-expanding sidewall in the distal portion capable of moving from a collapsed state within the catheter to an expanded state outside the catheter during deployment with an outer diameter greater than an outer diameter of the catheter,

the self-expanding sidewall further comprising a plurality of longitudinally etched slits in the self-expanding sidewall of the polymeric sheath thereby weakening structural integrity of sidewall while enhancing flexibility, the slits defining segments of the self-expanding sidewall each having a respective arcuate cross section in a plane orthogonal to a longitudinal axis of the sheath in the expanded state, wherein as the self-expanding sidewall is moved distally away from the distal end of the catheter, the slits cause the self-expanding sidewall to radially expand to an outer diameter that is greater than the inner diameter of the catheter;

wherein the self-expanding sheath and the catheter are advanceable in tandem over the guidewire such that as the distal end of the self-expanding sheath is moved distally relative to the catheter, the self-expanding sidewall expands to the expanded state; and

wherein the self-expanding sheath is removable from the lumen via the proximal end of the catheter.

9. The system of claim **8**, wherein the slits are spirals etched and disposed between proximal and distal ends of the self-expanding sheath, and wherein the slits enhance flexibility of the self-expanding sheath.

10. A polymeric self-expanding sheath for use with a catheter and a guidewire, the polymeric sheath comprising:

an outer surface slidably disposable in a lumen of the catheter;

an expandable element disposed on a distal portion approximate to a distal end of the self-expanding sheath, the expandable element capable of moving from a collapsed state within the lumen to an expanded state outside the lumen during deployment, the expandable element comprising a self-expanding sidewall comprising slits therein to define segments of the self-expanding sidewall each having a respective arcuate cross section in a plane orthogonal to a longitudinal axis of the sheath in the expanded state; and

an outer diameter of the expandable element being greater than an outer diameter of the catheter;

wherein the polymeric self-expanding sheath is capable of being advanced in tandem with the catheter over the guidewire such that as the distal end of the self-expanding sheath is moved distally relative to the catheter, the expandable element radially expands to the expanded state, and

wherein the self-expanding sheath is capable of being removed from the lumen via the proximal end of the catheter.

11. The sheath of claim **10**, wherein as the self-expanding sheath is moved distally away from the distal end of the catheter, the slits cause the outer diameter of the expandable element to be greater than the inner diameter of the catheter.

12. The sheath of claim **11**, wherein in the expanded state, the slits cause the expandable element to form a "pear-like" shape.

* * * * *